RESMED

S8 Elite™ II System
Clinical Guide

English

ResMed Ltd (Manufacturer) 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia • **ResMed Corp** (US Designated Agent) 14040 Danielson Street Poway CA 92064-6857 USA • **ResMed (UK) Ltd** (EU Authorised Representative) 96 Milton Park Abingdon Oxfordshire OX14 4RY UK • **ResMed Offices** Australia, Austria, Brazil, China, Finland, France, Germany, Hong Kong, India, Japan, Malaysia, Netherlands, New Zealand, Norway, Singapore, Spain, Sweden, Switzerland, UK, USA (see **www.resmed.com** for contact details).

Protected by patents: AU 697652, EP 0661071, US 5199424, US 5522382, US 6240921, US 6705315. Other patents pending.
Protected by design registrations: AU 302180, AU 302181, AU 302182, AU 302183, AU 302184, AU 302185, AU 302186, CN 200430121212.2, CN 200430121213.7, CN 200430121211.8, CN 200430121214.1, CN 200430121215.6, CN 200430121216.0, CN 200430121217.5, EP 269436, HK 0412901.9, JP 1257662, JP 1257663, JP 1266956, JP 1266957, JP 1267270, JP 1267271, NZ 405614, NZ 406923, NZ 406924, NZ 406925, NZ 406926, NZ 406927, NZ 406928, US D544598, US D553228, US D557406, US D557407. Others pending.
S8, S8 Elite, Mirage, HumidAire, HumidAire 3i, ResScan, Mirage Vista, Ultra Mirage, Mirage Activa, Mirage Swift, Mirage Liberty, Mirage Quattro, Papillon and SmartStart are trademarks of ResMed Ltd and HumidAire is registered in U.S. Patent and Trademark Office.

© 2008 ResMed Ltd. 338539/2 08 01

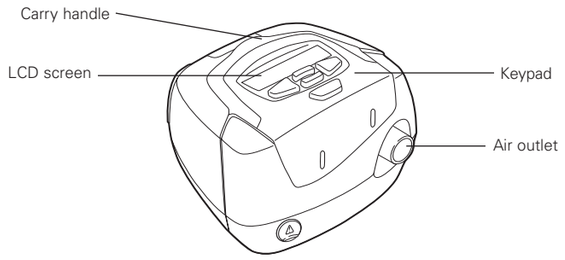
RESMED

S8 Elite™ II System

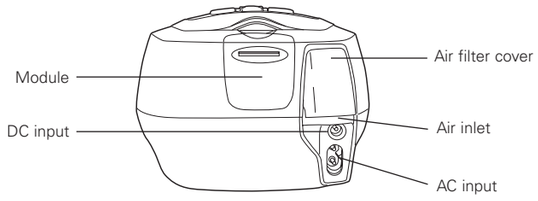
Component of 338539/2

ILLUSTRATIONS

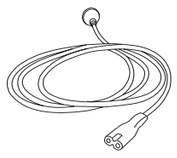
A SYSTEM COMPONENTS



1

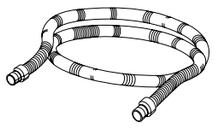


2



3

4

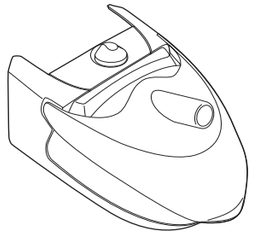


5

© 2008 ResMed Ltd.

Note: Some products not available in all regions.

B INTEGRATED HUMIDIFIER



HumidAire 3i™

© 2008 ResMed Ltd.

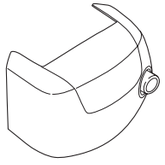
C OTHER ACCESSORIES

1

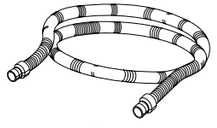
2

3

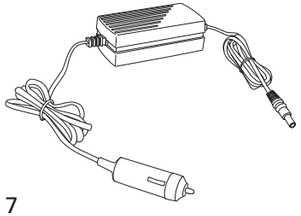
4



5



6

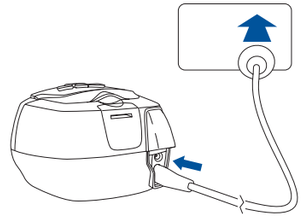


7

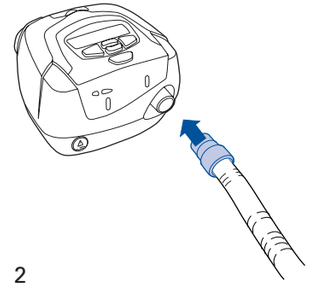
8

© 2008 ResMed Ltd.

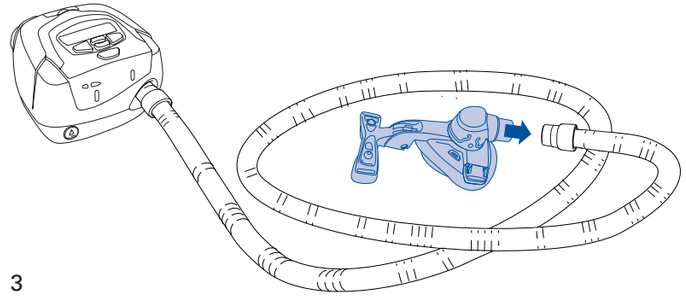
D SETTING UP THE S8™



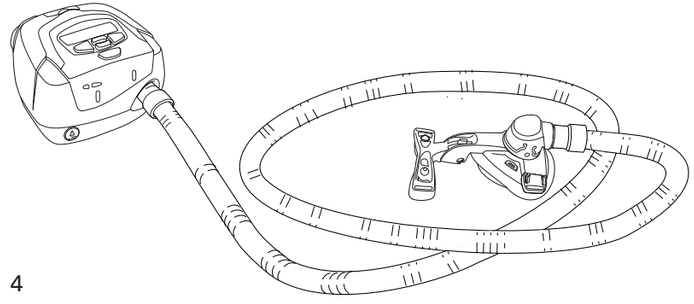
1



2



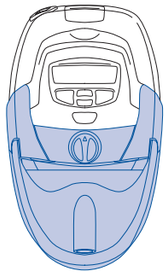
3



4

© 2008 ResMed Ltd.

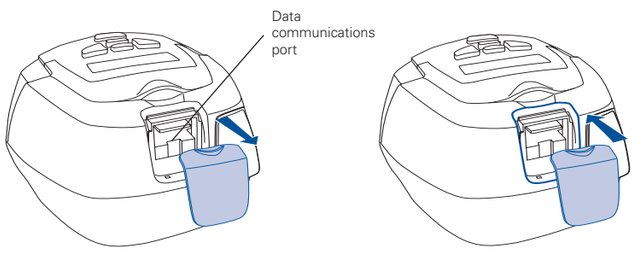
E HUMIDAIRE 3i



HumidAire 3i

© 2008 ResMed Ltd.

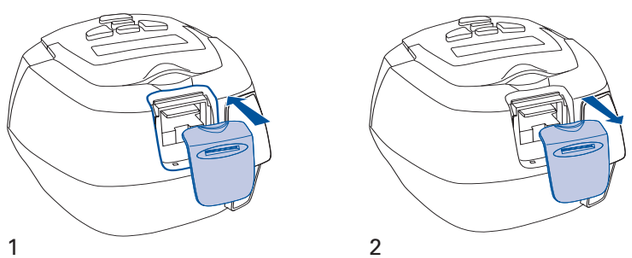
F BLANK MODULE



1 2

© 2008 ResMed Ltd.

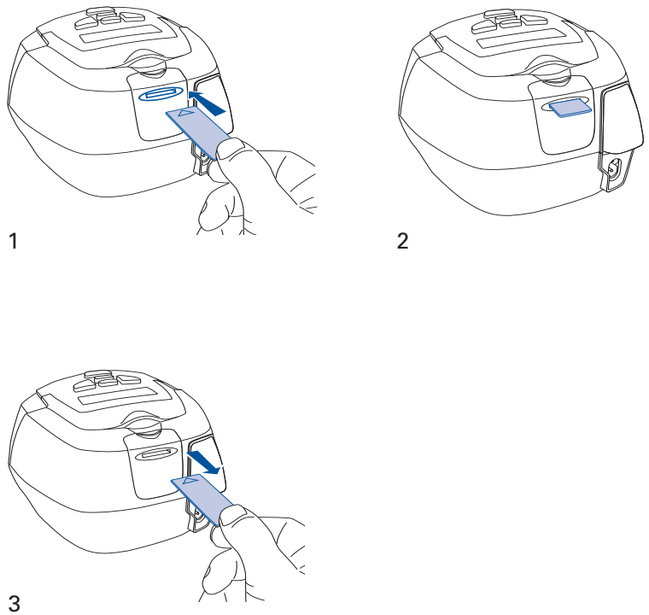
G DATA CARD MODULE



1 2

© 2008 ResMed Ltd.

H USING THE DATA CARD

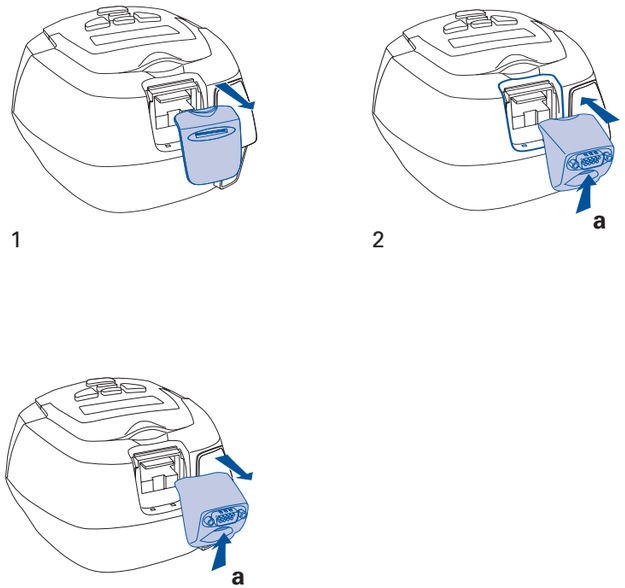


1 2

3

© 2008 ResMed Ltd.

I USING AN ADAPTER



1 2

3

© 2008 ResMed Ltd.

Note: Some products not available in all regions.

Contents

Introduction 1
User/Owner Responsibility 1
Medical Information 3
Indications for Use 3
Contraindications 3
Warnings 3
Cautions 4
Adverse Effects 5
The S8 Elite II System 7
S8 Elite II 7
Masks 7
Humidifier 8
Data Management Products 8
Accessories 8
Operating Information 9
Principles of Operation 9
System Setup 10
Delivering Therapy 11
Navigating the S8 Elite II Menus 14
S8 Elite II Keypad and LCD 14
S8 Elite II menus 15
Data Management Using the Menus 29
Clinical Menu Results 29
Interpreting Data in the Clinical Menu 31
Smart Data in the Patient Menu 32
S8 Data Management Products 35
Using a Blank Module 35
Using the ResScan Data Card Module 35
Patient Management of the Data Card 35
Transmitting Data with the Data Card 38
S8 Adapters 39
Cleaning and Maintenance 41
Daily Cleaning 41
Weekly Cleaning 41
Periodic Cleaning 41

Replacing the Air Filter 42
Servicing 42
Frequently Asked Questions 43
Troubleshooting 45
System Specifications 51
S8 Elite II (without Accessories) 51
Accessories 52
All Devices (where applicable) 52
Symbols which appear on the device 53
Index 55

Introduction

The ResMed S8 Elite™ II system is designed to provide continuous positive airway pressure (CPAP) therapy to patients with obstructive sleep apnea (OSA). The device delivers a fixed treatment pressure within the range 4 to 20 cm H_2O.

Patients with OSA experience recurrent obstruction of their upper airway (apneas) due to relaxation of the tongue and soft palate while they sleep. Common symptoms are associated with poor sleep quality and may include excessive daytime sleepiness and tiredness, as well as diminished concentration and memory loss.

Data storage and processing capabilities of the S8 Elite II system facilitate patient management. The system provides summary data for a variety of time intervals, which can be viewed via the LCD menus. The patient's usage hours, treatment pressure, mask leak, apnea + hypopnea index (AHI), apnea index (AI) and hypopnea index (HI) are displayed in the Results section of the clinical menu. At your discretion, the patient may view mask fit, treatment pressure and usage hours for the last session. This patient feature is called Smart Data™.

You can download the data stored in the S8 Elite II and review it in a PC-based software program. You can download the data directly, via cable. You can also access the data remotely, using a ResScan™ Data Card. A patient's therapy and reminder settings can also be updated using the software. Patient data can be accessed and S8™ device settings updated either via direct cable connection to the S8 Elite II or remotely, via a Data Card.

User/Owner Responsibility

The user or owner of this system shall have sole responsibility and liability for any injury to persons or damage to property resulting from:

- operation which is not in accordance with the operating instructions supplied
- maintenance or modifications carried out unless in accordance with authorized instructions and by authorized persons.

Please read this manual carefully before use.

This manual contains special terms and icons that appear in the margins to draw your attention to specific and important information.

- Warning alerts you to possible injury.
- Caution explains special measures for the safe and effective use of the device.
- Note is an informative or helpful note.

Medical Information

Indications for Use

The S8 Elite II CPAP system is indicated for the treatment of obstructive sleep apnea (OSA) in adult patients.

The S8 Elite II CPAP system is intended for home and hospital use.

CAUTION

In the US, Federal law restricts this device to sale by or on the order of a physician.

Contraindications

The S8 Elite II is not a life support device and may stop operating with power failure or certain fault conditions. It should not be used by patients who are dependent on continuous therapy.

Positive airway pressure therapy may be contraindicated in some patients with the following pre-existing conditions:

- severe bullous lung disease
- pneumothorax
- pathologically low blood pressure
- dehydration
- cerebrospinal fluid leak, recent cranial surgery or trauma.

Warnings

- The entire manual should be read before using the S8 Elite II.
- Advice contained in this manual should not supersede instructions given by the prescribing physician.
- A patient should not connect a device to the data communication port unless instructed to do so by their health care provider or physician. Only ResMed products are designed to be connected to the data communication port. Connecting other devices could result in injury, or damage to the S8 Elite II device.
- The S8 Elite II should be used with masks (and connectors*) recommended by ResMed, or by a physician or respiratory therapist. A mask should not be used unless the S8 Elite II device is turned on and operating properly. The vent hole or holes associated with the mask should never be blocked.

  Explanation: The S8 Elite II is intended to be used with special masks (or connectors*) which have vent holes to allow continuous flow of air out of the mask.

  When the device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask vent holes. However, when the device is not operating, insufficient fresh air will be provided

through the mask, and the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. This applies to most models of CPAP devices.

- In the event of power failure or machine malfunction, remove the mask.
- The S8 Elite II can be set to deliver pressures up to 20 cm H_2O. In the unlikely event of certain fault conditions, pressures up to 30 cm H_2O are possible.
- If oxygen is used with this device, the oxygen flow must be turned off when the device is not operating. If oxygen has been left on while the device is not operating, disconnect the oxygen and wait 30 minutes before turning on the device.

  Explanation: When the CPAP device is not in operation and the oxygen flow is left on, oxygen delivered into the air delivery tubing may accumulate within the CPAP machine enclosure and create a risk of fire. This applies to most types of CPAP machines.
  - Oxygen supports combustion. Oxygen should not be used while you are smoking or in the presence of an open flame.
  - Always ensure airflow is being generated by the device before the oxygen supply is turned on.
  - Always turn the oxygen supply off before stopping the airflow from the device.

  Note: *At a fixed rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on where the oxygen is introduced, the pressure settings, patient breathing pattern and leak rate.*
- Do not use the S8 Elite II if there are obvious external defects or unexplained changes in performance.
- Do not open the S8 Elite II case. There are no user serviceable parts inside. Repairs and internal servicing should only be performed by an authorized service agent.
- Explosion hazard—do not use in the vicinity of flammable anesthetics.

Cautions

- At low pressures, the flow through the exhalation ports of your mask may not clear all exhaled gas from the tubing. Some rebreathing may occur.
- The air flow for breathing produced by this device can be as much as 6°C higher than the temperature of the room. Caution should be exercised if the room temperature is warmer than 32°C.

Note: *The above are general warnings and cautions. Specific warnings, cautions and notes appear with the relevant instructions in the manual.*

---

* Ports may be incorporated in the mask or in connectors that are near the mask.

Adverse Effects

Patients should report unusual chest pain, severe headache, or increased breathlessness to their prescribing physician. An acute upper respiratory tract infection may require temporary discontinuation of treatment.

The following side effects may arise during the course of therapy with the S8 device:

- drying of the nose, mouth or throat
- nosebleed
- bloating
- ear or sinus discomfort
- eye irritation
- skin rashes
- chest discomfort.

The S8 Elite II System

A complete S8 Elite II system comprises the following elements:

- S8 Elite II flow generator
- Mask
- Humidifier
- Data management products
- Accessories.

S8 Elite II

The components of the S8 Elite II device are shown in the illustration sheet at the front of this manual:

- Front view (**A-1**)
- Rear view (**A-2**)
- Power cord (**A-3**)
- Travel bag (**A-4**)
- 2 m air tubing (**A-5**).

Masks

Patients will also need a **ResMed mask system** (supplied separately).

The ResMed mask systems that are recommended for use with the S8 Elite II are:

Nasal Masks

- Mirage Vista™ Nasal Mask
- Ultra Mirage™ II Nasal Mask
- Mirage™ Nasal Mask
- Mirage Activa™ Nasal Mask
- Silent Papillon™
- Papillon™.

Nasal Pillows Systems

- Mirage Swift™ Nasal Pillows System
- Mirage Swift™ II Nasal Pillows System.

Full Face Masks

- Mirage Liberty™ Full Face Mask
- Mirage Quattro™ Full Face Mask
- Ultra Mirage™ Full Face Mask.

Note: *Not all masks are available in all regions.*

WARNING

For optimal product performance and data recording, ResMed mask systems should be used with the S8 Elite II. Please refer to "Warnings" on page 3.

Humidifier

The S8 Elite II is compatible for use with the HumidAire 3i integrated heated humidifier (**B-1**).

See "Using Humidifiers" on page 13.

Data Management Products

The S8 Elite II will have either a ResScan™ Data Card module or a 'blank' module attached.

The following data management products may be purchased separately.

- ResScan Data Card (**C-1**)
- ResScan Data Card module (**C-2**)
- Serial adapter (**C-3**)
- USB adapter (**C-4**) and cable
- ResMed PC software.

Note: *Ensure that at least one module or adapter is connected to the S8 Elite II at all times.*

Accessories

The other accessories shown on the illustration sheet may also be purchased separately.

- Front cap (not available in all regions) (**C-5**)
- Air tubing 3 m (**C-6**)
- DC-12 converter (**C-7**)
- Blank module (**C-8**).

Note: *ResMed regularly releases new products. Please check our website at www.resmed.com.*

Operating Information

Principles of Operation

The S8 Elite II system is designed for clinical use and home treatment of adult patients with obstructive sleep apnea (OSA). The S8 Elite II device provides fixed-positive-pressure room air via tubing to the mask worn by your patient. The continuous air stream "splints" open the upper airway, preventing airway collapse.

The S8 Elite II delivers pressure within the range 4 to 20 cm H_2O, depending on the patency of the upper airway. To make the beginning of treatment more comfortable, you may set a ramp so the pressure starts low and gradually increases to full treatment pressure over the ramp time.

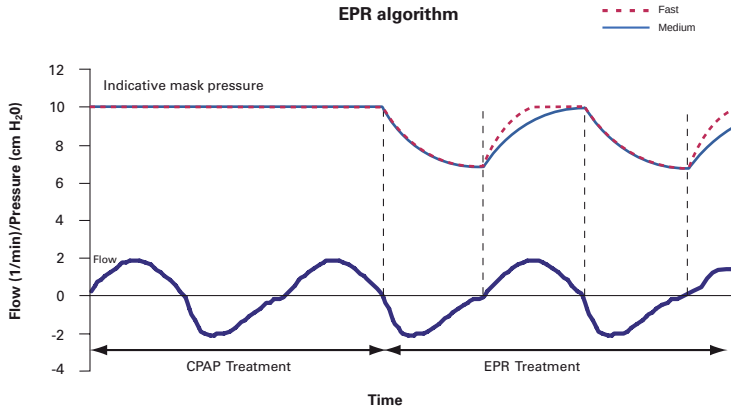
Expiratory Pressure Relief

Expiratory pressure relief (EPR) is designed to maintain optimal CPAP treatment for the patient during inhalation and reduce the delivered mask pressure during exhalation. The desired result of EPR is to decrease the pressure the patient must breathe out against, making the overall CPAP therapy more comfortable.

The features of EPR are:

- EPR is disabled automatically in the event of an apnea.
- EPR resumes automatically when the apnea event has passed.
- You can select an EPR pressure drop of OFF, 1, 2, or 3 cm H_2O.
- You can set EPR to be off, delivered only during ramping, or delivered throughout therapy.
- Pressure drop is limited, to avoid sub-optimal treatment (maximum drop is 3 cm H_2O).
- When EPR is enabled, the delivered pressure will not drop below a minimum pressure of 4 cm H_2O, even if, for example, the set pressure is 6 cm H_2O and the EPR level is 3.
- Either the clinician alone, or both the clinician and the patient can access the EPR level. You can enable or disable patient access to the EPR level setting.

The graph illustrates the performance of the S8 Elite II with the EPR inhalation settings.



System Setup

1 Place the S8 Elite II on a table near the head of the patient's bed.

CAUTION

Be careful to place the device where it cannot be bumped, and where no one will trip over the power cord.

Note: *The S8 Elite II device may be placed on the floor beside or underneath the patient's bed. Ensure that the area is free from dust and clear of bedding, clothes, or any other objects that could block the air inlet.*

2 Connect the AC power cord or ResMed DC-12 converter (not supplied) to the corresponding socket on the rear of the S8 Elite II (**D-1**). Plug the other end of the power cord or converter cable into the appropriate power outlet.

WARNING

- **Make sure the power cord and plug or adapter cable are in good condition and the equipment is not damaged.**
- **In the clinical environment any personal computer that is used with your CPAP system must be at least 1.5 m away from, or at least 2.5 m above, the patient. It must also comply with the relevant test standard. For personal computers the international standard is IEC 60950 or equivalent.**

3 Connect one end of the air tubing firmly onto the air outlet of the device (**D-2**) and the other end to the mask system (**D-3**).

When the S8 Elite II unit is powered up, the Welcome screen is displayed, followed by the standby (RAMP) screen.

The S8 Elite II system is now ready for use (**D-4**).

Note: *The S8 Elite II uses an internal pressure sensor, and therefore does not require calibration by a clinician or patient.*

SmartStart™

If you enable the SmartStart™ function, the patient's device will start automatically when they breathe into their mask, and will stop automatically when they take the mask off. This means that the patient does not have to press the **Start/Stop** key to begin or end treatment. See "Clinical Menu" on page 18. for details about enabling SmartStart.

Note: *A patient must not use SmartStart if they are using a mask with an anti-asphyxia valve, such as the Mirage Full Face Mask.*

Delivering Therapy

WARNING

A mask should not be used unless the S8 Elite II is turned on and operating properly.

1 Ensure the patient settings are correct.

Instruct the patient to lie down in bed, arrange the air tubing and put on the mask as in steps 1 and 2 in the section "Using the Mask Fitting Feature" on page 12.

WARNING

- Do not leave long lengths of air tubing around the top of the bed; they may twist around the patient's head or neck while they are sleeping.
- Blocking the air inlet or tubing while in operation could lead to overheating of the device.

2 Start therapy in one of two ways:

- If SmartStart is enabled, instruct the patient to breathe out strongly into the mask. The S8 Elite II device will start automatically.
- If SmartStart is not enabled, press the **Start/Stop** key to start the airflow. Air will begin flowing slowly and will build up to full operating pressure in about 15 to 25 seconds.

After starting therapy, the treatment pressure is displayed on the LCD.

Note: *The S8 Elite II measures pressure and compensates for air tubing and mask characteristics. The LCD shows the intended delivery pressure. If necessary, you can use a water manometer to take a more accurate reading.*

If the patient has difficulty falling asleep with full pressure, select a Ramp time. The airflow will start very gently while they fall asleep. The pressure slowly increases to full operating pressure over the selected Ramp time.

3 Instruct the patient to put on the mask according to the mask user instructions.

4 Adjust the mask and headgear to achieve optimal fit.

5 At the end of the ramp period, the LCD will display the word 'CPAP'.

6 Stop therapy in one of two ways:

- Remove the mask, and press the **Start/Stop** key to stop airflow.
- If SmartStart/Stop is enabled, simply remove the mask and treatment will stop automatically.

Using the Mask Fitting Feature

The S8 Elite II mask-fit feature delivers air pressure for a three-minute period before therapy begins for adjusting mask fit to minimize leak. It allows the patient to assess mask fit at typical treatment pressure at the start of the night, when pressure delivered is normally quite low.

The S8 Elite II system should be set up beside the patient's bed with the air tubing and mask system connected. (See "System Setup" on page 10.)

1 Instruct the patient to lie down in bed. If desired, place the tubing over the top of the headboard to reduce drag on the mask.

WARNING

Do not leave long lengths of air tubing around the top of the bed; they may twist around the patient's head or neck while sleeping.

2 Instruct the patient to put the mask on according to the mask user instructions.

3 Hold down the **Start/Stop** key on the control panel (see Figure 1, S8 Elite II Keypad and LCD, on page 14) for at least 3 seconds until pressure delivery starts and the following screen appears:

Note: *The mask-fit pressure is the set treatment pressure, or 10 cm H_2O, whichever is greater.*

4 Adjust the mask, cushion and headgear to achieve optimal fit.

Table 1: Star ratings for the mask-fit and patient Smart Data features

Star rating	Indicative Leak Measure (L/s)	(L/min)
* * * * * (Excellent)	0.00–0.18	0.0–10.8
* * * * _ (Very good)	0.19–0.26	10.9–15.6
* * * _ _ (Good)	0.27–0.34	15.7–20.4
* * _ _ _ (Adjust mask)	0.35–0.41	20.5–24.6
* _ _ _ _ (Adjust mask)	0.42–0.49	24.7–29.9
_ _ _ _ _ (Adjust mask)	≥ 0.50	≥ 30

Note: *While using the mask-fit feature, the star rating values are indicative of the instantaneous leak calculated over the last 10 seconds.*

Smart Data (designed for the patient) also uses a star rating for mask fit. The Smart Data star rating values correspond to 70th centile mask leak for the last session. A five-star rating is displayed, for example, if the leak rate was less than 0.10 L/s for 70% of the session.

5 After three minutes, the pressure will revert to the set pressure, and treatment will begin.

- If you do not wish to wait three minutes, **hold down** the **Start/Stop** key for three seconds and treatment will begin immediately.
- If you **press** the **Start/Stop** key briefly (ie, for less than three seconds), the device will return to standby mode (the RAMP screen is displayed).

Using Humidifiers

Please refer to the illustration in section **E** of the illustration sheet and your HumidAire 3i manual.

The HumidAire 3i humidifier attaches to the front of the S8 Elite II to provide heated humidification. No other accessories are required for its use.

Notes:

a. Make sure the water chamber of the HumidAire 3i is empty before you attach or detach the humidifier.

b. Remove the connector plug on the S8 Elite II before you attach the HumidAire 3i. Reattach the connector plug firmly after you detach the humidifier.

Storing the HumidAire 3i

Store the HumidAire 3i in its mesh-top pouch in the S8 Elite II travel bag when not in use.

Navigating the S8 Elite II Menus

S8 Elite II Keypad and LCD

The control panel of the S8 Elite II includes a keypad for navigating through the menus and delivering treatment.

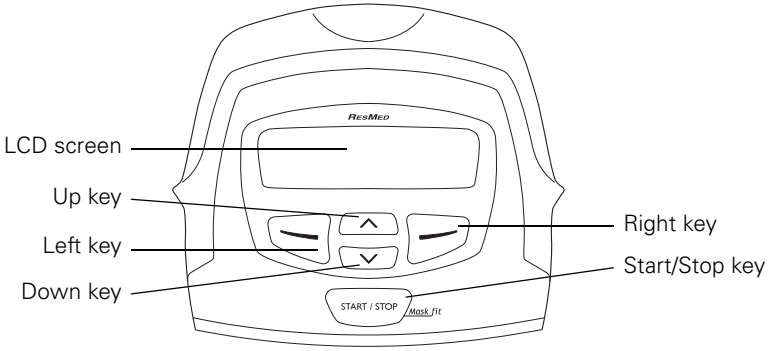


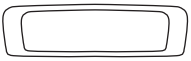
Figure 1: S8 Elite II Keypad and LCD

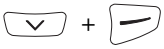
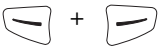
The LCD is used to display the menus and other data. The arrows and lowercase text on the bottom line of the LCD prompt the use of the keys within the menus.

The keypad is used to navigate through the menus, access the mask-fit feature and start/stop treatment. The functions of the keys and quick key combinations are listed in Table 2.

The LCD backlight turns off after two minutes of inactivity. It turns back on when you press a key.

Table 2: Keys on the front panel and their functions

Key	Function
LCD screen 	• Displays S8 Elite II information including the menus and treatment screens.
Start/Stop	• Starts or stops treatment. • Extended hold for at least three seconds starts the mask-fit feature.
Up	• Navigates between items within the menu. • Allows you to increase settings options.
Down	• Navigates between items within the menu. • Allows you to decrease settings options.

Key	Function
Left	• Performs the function indicated by the guiding text displayed above it on the LCD (eg, change).
Right	• Performs the function indicated by the guiding text displayed above it on the LCD (eg, exit). • Extended hold (for at least 3 seconds) returns you to the standby screen (if you are in the patient menu) or the CLINICAL MENU screen (if you are in the clinical menu). • Returns you to the standby screen from the CLINICAL MENU screen.
Down + Right 	• Extended hold (for at least 3 seconds) gives access to the clinical menu from the standby screen.
Left + Right 	• Extended hold (for at least 3 seconds) gives quick access to the Quickview menu Settings section (for patients to view their device settings in read-only mode) and the Results section only. It does not allow further navigation (eg to other sections of the clinical menu). See Figure 7, Quickview menu screens, on page 22, and Figure 8, The clinical menu results series, on page 30.

When the S8 device is in standby mode all keys remain lit. During therapy, the keypad backlight turns off after two minutes of inactivity and the **Start/Stop** key dims.

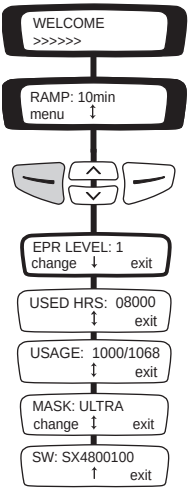
S8 Elite II menus

The S8 Elite II LCD displays a variety of submenus, parameters and data. Whether the machine is in standby mode, or delivering therapy, you can view and change settings. When the S8 Elite II is first turned on, the Welcome screen appears while the device is performing self-checks.

Patient Menu

Depending on what menu type you have set in the clinical menu, the patient will see a standard or detailed menu.

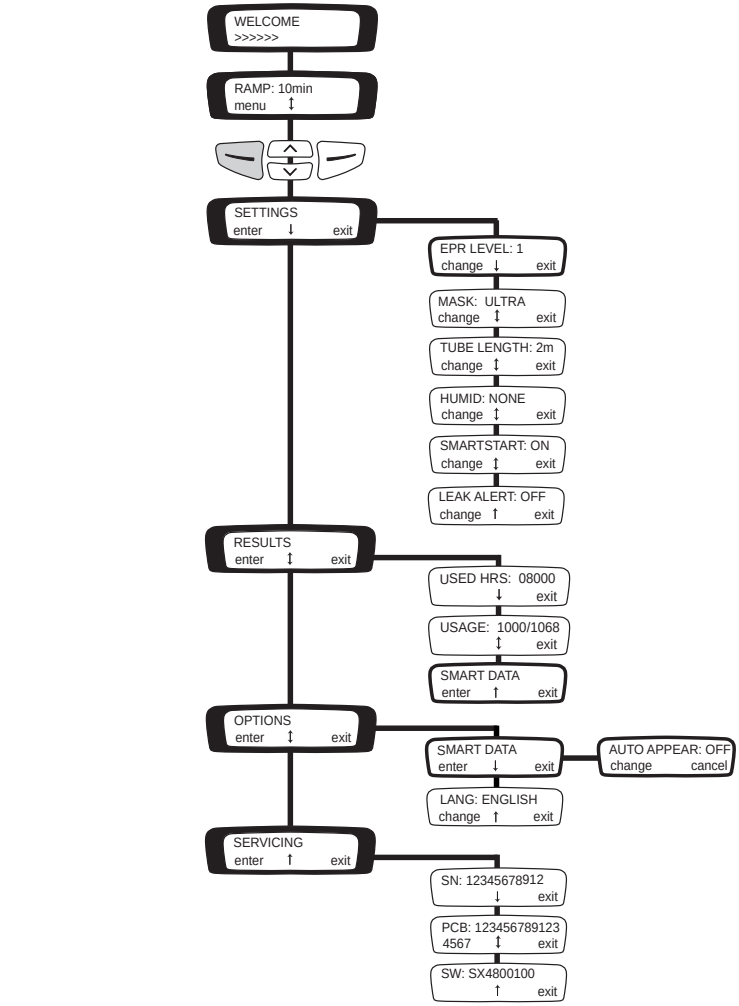
Figure 2 summarizes the standard patient menu series.



This screen appears only if access is enabled by a clinician.

Figure 2: Standard patient menu series

Figure 3 summarizes the detailed patient menu series.



These screens appear only if access is enabled by a clinician.

Figure 3: Detailed patient menu series

To navigate and make selections within the patient menu, use:

- the **Up/Down** keys to scroll through items within a level
- the **Left** key to enter a submenu and to apply an option choice
- the **Right** key to navigate out of a menu or submenu, and to exit without changing options.

Note: *The Results menu and Smart Data in the Options menu are displayed only if you have set one or more Smart Data options to ON in Clinical Menu, Options, Smart Data.*

Parameters in the standard and detailed patient menus are described in Table 3 on page 23. Those parameters that appear in one or both patient menus and the clinical menu are marked with an asterisk (*).

Clinical Menu

Access the clinical menu from the standby screen by holding down the **Right** and **Down** keys simultaneously for at least three seconds.

The flow charts in Figures 4–6 summarize the clinical menu series. For an expanded view of the Results section, see Figure 8, The clinical menu results series, on page 30.

To navigate and make selections within the clinical menu, use:

- the **Up**/**Down** key to scroll through items within a level
- the **Left** key to enter a submenu and to apply an option choice
- the **Right** key to navigate out of a menu or submenu, and to exit without changing options.

Parameters in the clinical menu are described in Table 3, "Descriptions of parameters in the patient menu and the clinical menu," on page 23.

EPR (expiratory pressure relief)

You can switch EPR off completely, set it for use during ramp only, or set it for full-time use during therapy (including the ramp period).

You can either set the EPR level only, or you can set the EPR level and enable patients to modify their level of EPR via the EPR LEVEL screen in the patient menus.

Figure 4 shows the main menu screens. The Settings menu is expanded in Figure 5. The Options menu is expanded in Figure 6.

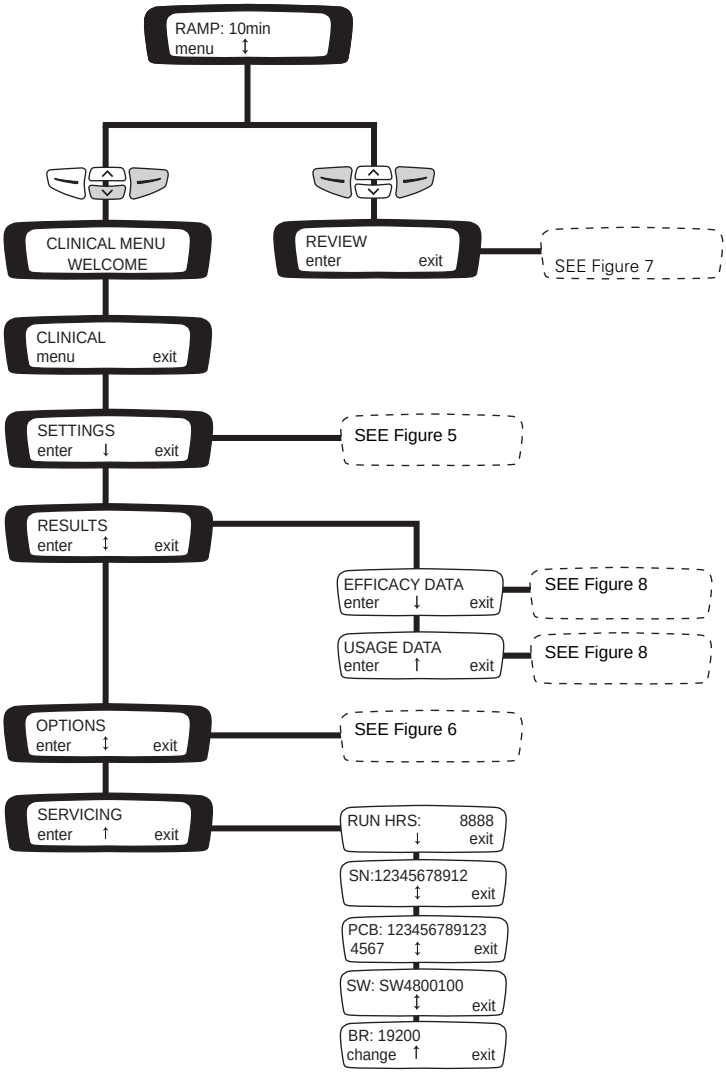


Figure 4: Clinical menu series

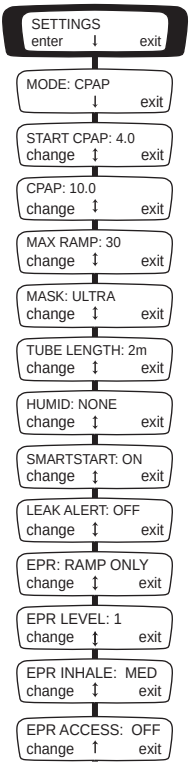


Figure 5: Settings menu screens

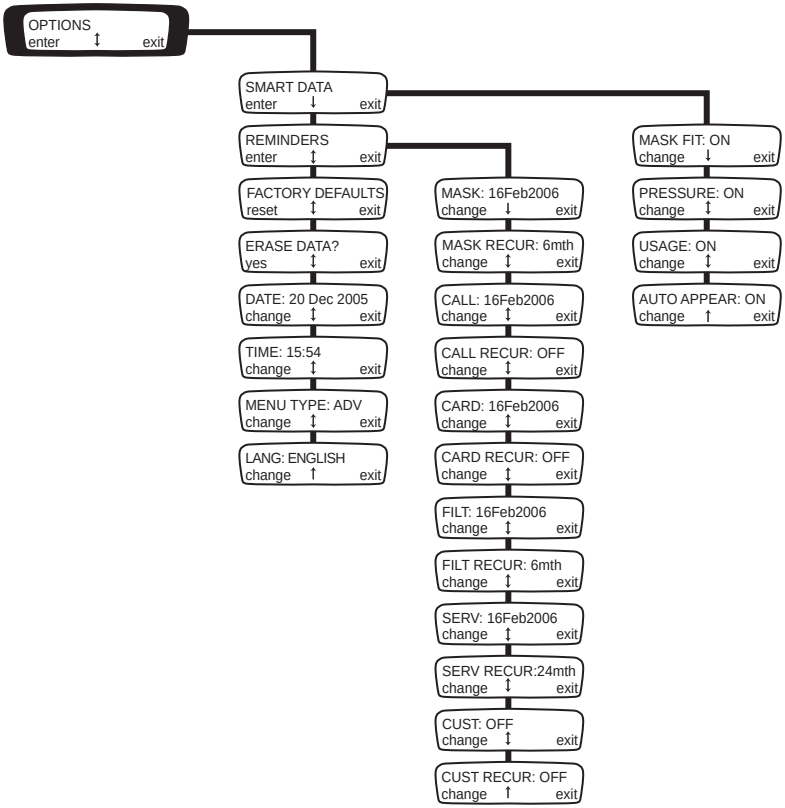


Figure 6: Options menu screens

QuickView

Note: *QuickView is accessible by patients.*

QuickView provides a quick, read-only way for a patient to access their device settings. This is useful if you cannot see the patient's device and you want them to provide details of their current settings and efficacy data remotely.

QuickView is accessed by holding down the **Right** and **Left** keys simultaneously for 3 seconds.The screens in Figure 10 are then available to the patient.

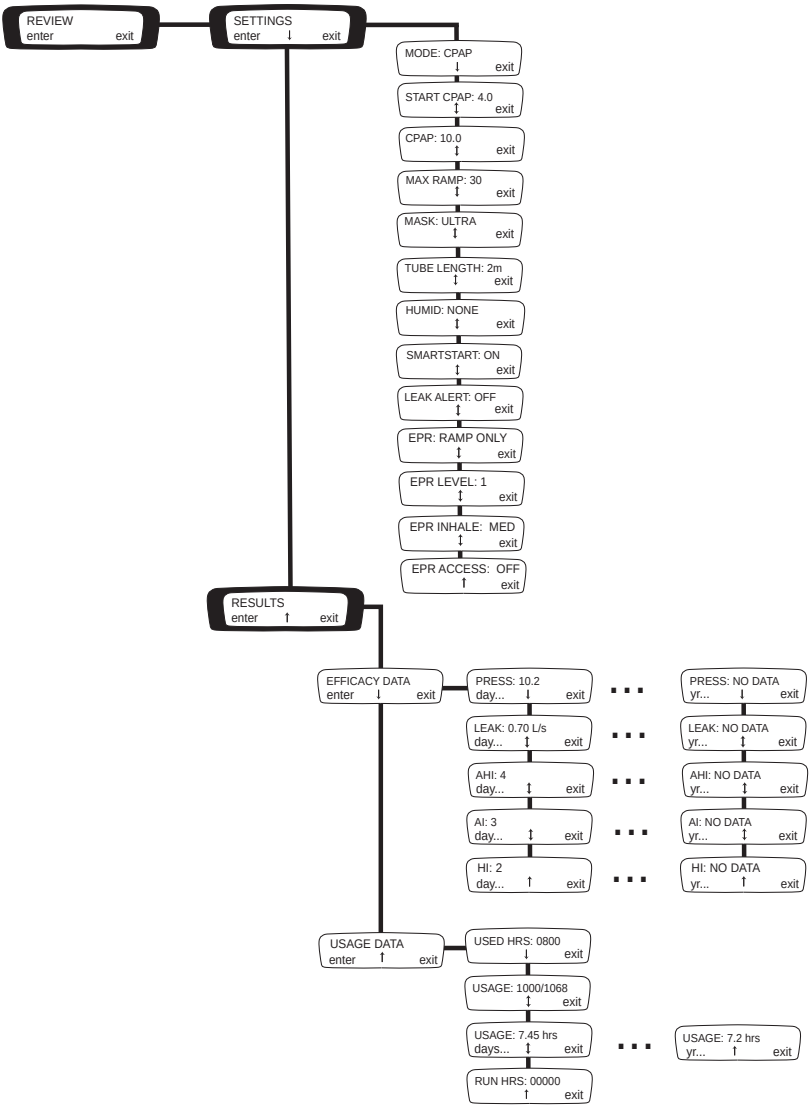


Figure 7: Quickview menu screens

Table 3: Descriptions of parameters in the patient menu and the clinical menu

Menu	Parameter	Description
	Ramp*	Sets the ramp time.
	Used Hrs*†	Displays the total number of treatment hours. (View only.)
	Usage*†	The number of used sessions greater than 1 minute in length over the number of days elapsed since the first used day.
Settings	Mode	Displays the therapy mode. (View only)
	Start CPAP	Sets the pressure at the start of the ramp up to fixed treatment pressure.
	CPAP	Sets the fixed treatment pressure.
	Max Ramp	Limits the ramp times the patient may select.
	Mask*	Sets the mask type. *Note: when the mask type is MIR FULL, SmartStart/Stop is automatically disabled.*
	Humid*	Provides a setting option for a humidifier or front cap, if one is required. (Automatically detects the presence of a HumidAire 3i.)
	Tube Length*	Sets the length of the air tubing used.
	SmartStart*	Enables or disables the SmartStart/Stop feature; when enabled, the device will start automatically when the patient breathes into the mask, and stop automatically when the patient takes the mask off.
	Leak Alert*	Enables or disables the Leak Alert feature; when enabled, leaks > 0.7 L/s for > 20s result in an audible alert and a high leak message in the LCD. *Note: when Leak Alert is enabled, SmartStart/Stop is automatically disabled.*
	EPR	Sets expiratory pressure relief to occur all the time, during ramping only, or never.
	EPR Level*	Sets the expiratory pressure relief value. This screen is not displayed if EPR is set to OFF. *Note: EPR LEVEL only appears in the patient menu if you have set patient access to EPR.*
	EPR Inhale	Sets the rate at which pressure returns to therapy pressure during inhalation.

Menu	Parameter	Description
	EPR Access	Enables or disables patient view of, and ability to change, EPR level. This screen is not displayed if EPR is set to OFF.
Results	Efficacy Data	Displays pressure, leak, AHI (apnea + hypopnea index), AI (apnea index) and HI (hypopnea index) data for a range of time intervals. For details, see "Clinical Menu Results" on page 29.
	Usage Data	Displays usage data (including Run Hours) for a range of time intervals. For details, see "Clinical Menu Results" on page 29.
Options	Smart Data*	Allows the clinician to select which Smart Data screens, if any, are displayed in the patient menu. *Note: if you wish to make Smart Data available, set one or more of the options (Mask Fit, Pressure, or Usage) to ON. Set Auto Appear to ON so that the Smart Data screens are displayed in the morning if the patient resets the device.* In the patient menu, the Smart Data menu is displayed only if one or more of the options have been set to ON by the clinician. If AutoAppear is set to OFF, Smart Data is displayed in the Results menu only.
	Reminders	Enables you to schedule and/or create reminder messages for a patient, via a number of submenu screens. See "Setting Reminders" on page 25. You can also set individual reminders to recur at intervals from 1 to 24 months. See "Setting Reminder Recurrence" on page 27.
	Factory Defaults	Resets machine default settings (except for Language, Date and Time).
	Erase Data?	Allows the clinician to erase all data stored in the device (except for Run Hours). Settings are not affected.
	Date	Sets the current date.
	Time	Sets the current time.
	Menu Type	Sets the menu that the patient will see: standard (STD) or detailed (ADV).
	Language*	Sets the display language.

Menu	Parameter	Description
Servicing	Run Hours*	Displays the total number of machine hours. (View only)
	SN*	Displays the device serial number. (View only)
	PCB*	Displays the printed circuit board number. (View only)
	SW*	Displays the current software version.
	BR	Sets the baud rate. This value is reset to 19200 every time the S8 Elite II is powered up.

* These parameters may appear in one or both patient menus and the clinical menu.
† More detailed data is available via your PC application.

Note: *When Leak Alert is set to ON, SmartStart/Stop is automatically set to OFF. SmartStart/Stop cannot be used with Leak Alert because, if a high leak occurs, SmartStop may stop treatment before the Leak Alert signal is activated.*

Settings for Mask Types

The following table shows the setting that should be selected for each mask type.

Settings	Mask
ULTRA	Ultra Mirage II Nasal Mask
MIR FULL	Mirage Liberty Full Face Mask Mirage Quattro Full Face Mask Ultra Mirage Full Face Mask
ACTIVA	Mirage Activa Nasal Mask
SWIFT	Mirage Swift Nasal Pillows System Mirage Swift II Nasal Pillows System
MIRAGE	Mirage Nasal Mask
STANDARD	Mirage Vista Nasal Mask Silent Papillon Papillon

Setting Reminders

You can set a number of reminders to alert the patient to specific events; for example, when to replace their mask, when to insert a Data Card (if their device is Data Card enabled) and so on. You can also set special customized reminders.

When a reminder is due, a message is displayed on the LCD and remains whenever the device is not delivering therapy. The backlight on the LCD flashes when a message is displayed.

If more than one reminder for a patient is scheduled for the same date, all scheduled reminders are displayed on that date. Patients can clear each message by pressing the **Left** key (or inserting a Data Card, in the case of the Data Card reminder).

You access reminders from Clinical Menu, Options (see Figure 5, Settings menu screens, on page 20). From the REMINDERS screen, scroll down to the submenus to set a number of different types of message.

Replace mask

You can set a timed reminder to remind a patient when they need to replace their mask. The patient can press the **Left** (Ok) key to remove the message from the LCD.

Call Provider

You can set a timed reminder for your patient to phone you at a certain time; for example, to discuss how their therapy is going. The patient can press the **Left** (Ok) key to remove the message from the LCD.

Insert Card

If a patient's flow generator is Data Card enabled, you can set a timed reminder on the flow generator to remind them that they need to insert a Data Card to transfer patient data. This enables you to establish compliance. The patient should actually insert the Data Card in order to clear the message from the LCD. (They can also press the **Left** (Ok) key to remove the message.)

Replace filter

You can set a timed reminder to remind your patient when to replace the air filter. The patient can press the **Left** (Ok) key to remove the message from the LCD.

Service Due

You can set a timed reminder to remind your patient when to return the device for service. The patient can press the **Left** (Ok) key to remove the message from the LCD.

Customized messages

You can also set reminders for other reasons; for example, to return equipment or to phone a particular person or number. You can make the custom reminder text up to 16 characters long, via PC application software. See your PC application manual for more information.

The following table shows the options and default settings for the types of reminders you can set.

Type of reminder	Reminder date*	Recurrence period
Replace mask (MASK)	7-day increments, starting from the current set date	1–24 months
Call provider (CALL)	7-day increments, starting from the current set date	1–24 months

Type of reminder	Reminder date*	Recurrence period
Insert Card (CARD)	7-day increments, starting from the current set date	1–24 months
Change filter (FILT)	7-day increments, starting from the current set date	1–24 months
Service due (SERV)	7-day increments, starting from the current set date	1–24 months
Customized reminder (CUST)	7-day increments, starting from the current set date	1–24 months

* If you have used a PC application to set a reminder date, and you later change that date using the S8 Elite II Reminder screens, you can only change it in 7-day increments.

Setting Reminder Recurrence

You can set each reminder to keep re-occurring at a specific time period, starting from the date set for the original reminder. You can set the recurrence time period from 1 month to 24 months. (Each month in the recurrence time period is equal to 30 days.)

You have to set a date for a specific reminder before its recurrence time period will take effect.

For example, if you set a REPLACE MASK reminder for 30 August 2008, the patient will see that reminder on 30 August 2008. If you have also set a MASK RECUR reminder for 6 months, the mask reminder will occur again 6 months (180 days) from the date the reminder is acknowledged by the patient. The mask reminder will continue to recur at 6-month intervals unless you change the recurrence period, or set the mask reminder to OFF.

You access reminder recurrences from Clinical Menu, Options (see Figure 9, Options menu screens, on page 24). From the REMINDERS screen, scroll down to the submenus to set recurrences for the different reminders.

Data Management Using the Menus

The S8 Elite II system may be used to monitor patient usage as well as treatment pressure, mask leak and incidence of apneas and hypopneas. To assess the patient's progress, data for the last session may be compared to median values for the last week, the last month, the last six months and the last year, as displayed in the Results menu. The device stores usage and summary data for up to 365 sessions.

Comprehensive patient data can be viewed either on the LCD or in a PC software application. Data and settings can be transferred between the S8 Elite II and the PC application via S8 data management products. See "S8 Data Management Products" on page 35.

Clinical Menu Results

A comprehensive set of data (usage data and efficacy data) is available in Clinical Menu, Results, as shown in Figure 8 on page 30.

To navigate within the Efficacy or Usage Data screens, use:

- the **Up/Down** key to scroll through items within a time series
- the **Left** key to navigate between time series.

The USED HRS screen reports the total hours the device has been used and the first USAGE screen reports the number of sessions the device was used, compared to the total sessions since the last time the compliance data was reset. Other USAGE screens report statistical usage data.

Other statistics quoted include:

- usage
- pressure (95th centile value for mask-on time only)
- leak (95th centile value for mask-on time only)
- AHI: apnea + hypopnea index (calculated per session)
- AI: apnea index (calculated per session)
- HI: hypopnea index (calculated per session).

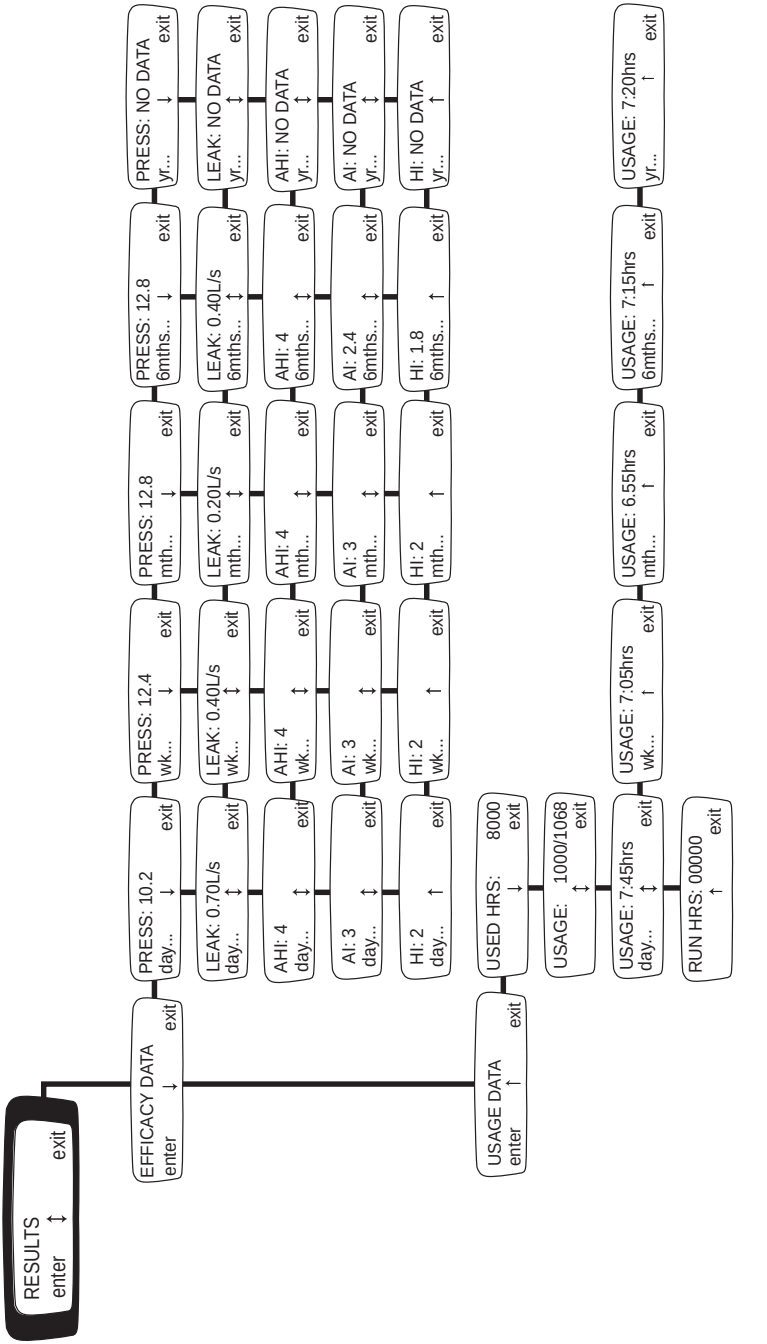


Figure 8: The clinical menu results series

Statistics are provided for five time intervals (last day, last week, last month, last six months, last year) so you can assess the significance of recent events.

All statistics calculated for a range of dates are median values. The median is the middle value after the data have been sorted in order (50% of the values are smaller and 50% are larger). For example, Table 4 presents one week of 95th centile leak data (values in L/s). On day 7, the value 0.30 L/s would be displayed as the most recent day's leak value. In column 3 of the table, the seven leak values have been sorted in increasing order to calculate the median value.

Table 4: Sample calculation of median leak value

Day	95th centile leak (L/s)	Ordered data set (L/s)	Median value (L/s)
7	0.30	0.20	
6	0.20	0.20	
5	1.00	0.30	
4	0.20	0.30	0.30
3	0.30	0.30	
2	0.40	0.40	
1	0.30	1.00	

The median corresponds to the fourth value (0.30 L/s) in the ordered data set. The value 0.30 L/s would be displayed as the most recent week's leak value.

If the data set had included an even number of days (eg, a 30-day month), the median would be the average of the middle two values in the ordered data set.

Notes:

a. *The median is a more robust measure than an average (or arithmetic mean) for a data set that has some extreme values. The average of the data in the above table is 0.39 L/s, reflecting the single session that had unusually high leak (1.00 L/s).*
b. *You may make the Efficacy and Usage Data screens available to your patient by instructing them to press the* **Left** *and Right keys simultaneously. This does not give access to the other parts of the clinical menu.*

The Erase Data feature in Clinical Menu, Options enables you to remove all efficacy and usage data stored in the device (except Run Hours). Machine settings are not affected.

Interpreting Data in the Clinical Menu

Note: *When assessing results, check the leak data first. Leak values greater than 0.4 L/s (24 L/min) affect the accuracy of other measurements.*

Pressure

The pressure transducer located in the device measures treatment pressure; the average pressure is calculated and recorded each minute. The pressure reported in the Efficacy Data submenu (see Figure 8, The clinical menu results series, on page 30) for a single session is the 95th centile pressure for mask-on time, excluding periods when the leak has exceeded 0.4 L/s (24 L/min). For selected time intervals (last week, last month, last six months, or last year), the median of the daily 95th centile values is reported. Non-usage days are not included in calculations.

Leak

Leak is derived by analyzing inspiratory and expiratory airflows (via the flow sensor located in the device). Theoretically, inspiratory and expiratory volumes should be equal. A net airflow greater than the expected mask vent flow is equal to the leak. Generally, a leak rate of more than 0.4 L/s (24 L/min) is associated with patient discomfort, disturbed sleep and reduced efficacy of treatment.

Notes:

a. *If the leak exceeded 0.4 L/s (24 L/min) for more than 30% of the previous session, the following message will appear on the LCD: High leak in last session.*

b. *The Leak Alert feature, if enabled, will alert the patient when mask leak exceeds 0.7 L/s (42 L/min) for more than 20 seconds.*

The leak reported in the Efficacy Data submenu (see Figure 8, The clinical menu results series, on page 30) is the 95th centile value for mask-on time for each session, or the median 95th centile value for a selected time interval (last week, last month, last 6 months, or last year). Non-usage days are not included in calculations.

Apneas and hypopneas

An **apnea** is defined as a greater than 75% decrease in ventilation. The device algorithm scores an apnea if the 2-second moving average ventilation drops below 25% of the recent time average (time constant 100 seconds) for at least 10 consecutive seconds. A **hypopnea** is defined as a 50 to 75% drop in ventilation. A hypopnea is scored if the 8-second moving average ventilation drops below 50%, but not below 25%, of the recent average for 10 consecutive seconds.

The AHI, AI and HI reported in the Efficacy Data submenu are calculated values per usage hour per session, or median values for a selected time interval (last week, last month, last six months, or last year).

Smart Data in the Patient Menu

A Smart Data feature has been incorporated in the S8 Elite II device to increase patient involvement in their therapy. Display of Smart Data for the patient to review is at your discretion. Select some or all options for display in the patient

menu from the Smart Data submenu in Clinical Menu, Options (see Figure 6, Options menu screens, on page 21). The following data can be made available, showing, for the most recent session:

- the star rating of the 70th centile mask fit
- 95th centile pressure
- total duration of session (usage).

Set the Mask Fit, Pressure or Usage options to ON to enable the patient to see any or all of this data.

If the Auto Appear option is set to OFF, the data will be displayed in the Results submenu of the patient menu only. If you (or the patient) set Auto Appear to ON, the data for the previous session will be displayed after the patient restarts the device.

Data for the current session are available for display up until noon, when a new session commences.

Note: *If none of the Smart Data options (Mask Fit, Pressure or Usage) has been set to ON in the clinical menu, the Results submenu is not displayed in the patient menu.*

Patients can use a Smart Data diary to monitor their therapy. You can download a PDF of the Smart Data diary for S8 Elite II from *www.resmed.com*.

S8 Data Management Products

Note: *Do not remove data management products from the S8 Elite II while power is connected.*

The S8 Elite II will have one of two modules fitted to the back:

- blank module
- Data Card module.

Serial and USB adapters are also available, for transferring data to a PC.

Using a Blank Module

The blank module is a protective cover on the S8 Elite II. At times, you may wish to remove or attach the module, for example to use an adapter.

To remove the blank module, pull it off the back of the S8 Elite II to show the data communications port (**F-1**).

To *attach* the blank module, push the blank module onto the data communications port, until the module clicks into place (**F-2**).

Note: *To protect the data communications port, always ensure there is a module attached to the back of the device.*

Using the ResScan Data Card Module

The ResScan Data Card module is a convenient way of gaining remote access to the data stored in the S8 Elite II, and of updating the settings in the S8 Elite II. The Data Card module is for home and hospital use. This module uses the ResScan Data Card for data collection and transmission.

Note: *Patient compliance data stored in the S8 Elite II remains unchanged when copied to the Data Card.*

If a patient has an S8 Elite II with a Data Card module attached, they can use a Data Card to retrieve data or update settings that are stored in the S8 Elite II.

If a patient has an S8 Elite II with a blank module attached, and they need to use a Data Card, you can order a Data Card starter pack from ResMed. This pack contains a Data Card module and Data Card.

1. Remove the blank module from the S8 Elite II (**F-1**).
2. Attach the Data Card module to the S8 Elite II (**G-1**).
3. Follow the instructions for inserting the Data Card (page 37).

Patient Management of the Data Card

Before issuing the Data Card, make sure that it has been labeled with the patient's ID and is correctly addressed. Refer to "Using the Mailback Envelope" on page 36 for more details.

Check that the patient knows:

- why they are being issued with a Data Card

- when and how they must use the Data Card
- how to insert the Data Card
- how to remove the Data Card
- how to return the Data Card
- where to look for information (the "Troubleshooting" section of the User Guide for their S8 device) if the data transfer does not work as expected.

Labeling the Data Card

- We strongly advise that you write the patient's identification details on the Data Card to prevent any mix-up of patient data. A space is provided on the Data Card for this purpose.
- Each Data Card is reusable. If you are issuing an existing Data Card to a new patient, make sure that the card is labeled with the new patient's ID. Use the space provided on the Data Card label when issuing a new card.

Notes:

a. When reusing a Data Card, make sure that you use a label that does not cover more than the ID area on the Data Card, and is not more than 0.2 mm thick. If the label is larger than this, the patient may not be able to insert the Data Card into the Data Card module on their flow generator.

b. If you reuse a Data Card that already has a label on it, remove the old label before attaching a new one.

Supplying the Data Card

You can monitor a patient's treatment with the Data Card and mailback envelope supplied with their device. The patient can return the card to you when they have copied their data onto it.

Ensure that the patient knows that they must remove their Data Card from the device when they have finished copying data to it. Leaving the Data Card in the device during therapy will not result in additional data being copied to the card. If a patient needs to copy additional data to the Data Card, they will need to insert the card again.

If you want a patient to update the settings in their S8 Elite II, you can load the new settings on to a Data Card and either give or mail them the card. The patient can return the card to you when they have applied the settings on their S8 device. The information on the card will allow you to assess whether the patient's settings have been changed as expected.

Notes:

a. The Data Card should be stored in its mailback envelope when not in use.

b. Use a postal envelope to mail the mailback envelope and its contents to the patient.

Using the Mailback Envelope

The Data Card slots into the mailback envelope to keep it safe while in transit or storage.

Figure 9 shows the inside of the mailback envelope.

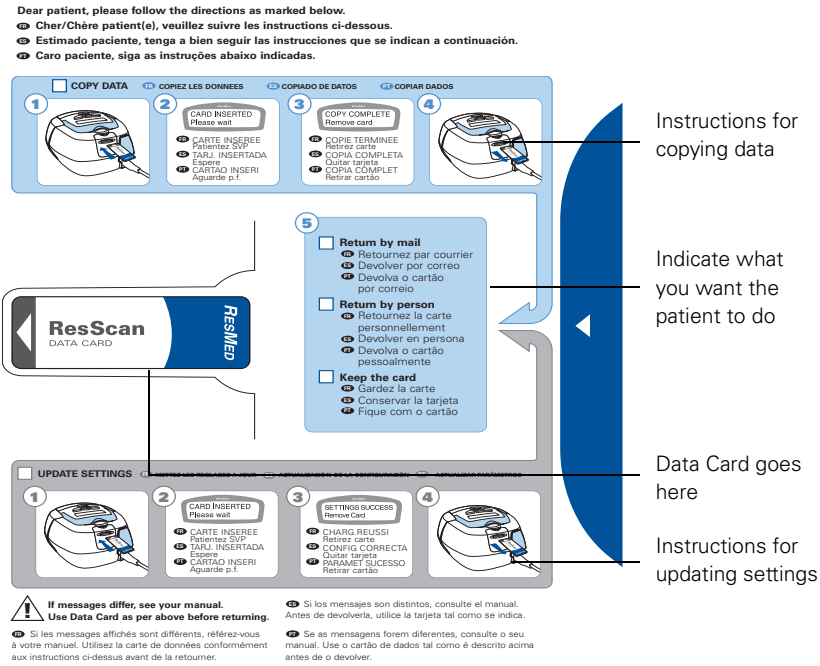

Dear patient, please follow the directions as marked below.
Cher/Chère patient(e), veuillez suivre les instructions ci-dessous.
Estimado paciente, tenga a bien seguir las instrucciones que se indican a continuación.
Caro paciente, siga as instruções abaixo indicadas.
COPY DATA
COPIEZ LES DONNEES
COPIADO DE DATOS
COPIAR DADOS
CARD INSERTED Please wait
CARTE INSEREE Patientez SVP
TARJ. INSERTADA Espere
CARTAO INSERI Aguarde p.f.
COPY COMPLETE Remove card
COPIE TERMINEE Retirez carte
COPIA COMPLETA Quitar tarjeta
COPIA COMPLET Retirar cartão
Instructions for copying data
Return by mail
Retournez par courrier
Devolver por correo
Devolva o cartão por correio
Return by person
Retournez la carte personnellement
Devolver en persona
Devolva o cartão pessoalmente
Keep the card
Gardez la carte
Conservar la tarjeta
Fique com o cartão
Indicate what you want the patient to do
ResScan
DATA CARD
ResMed
UPDATE SETTINGS
SETTINGS SUCCESS Remove Card
CHARG.REUSSI Retirez carte
CONFIG CORRECTA Quitar tarjeta
PARAMET SUCESSO Retirar cartão
Data Card goes here
Instructions for updating settings
If messages differ, see your manual.
Use Data Card as per above before returning.
Si les messages affichés sont différents, référez-vous à votre manuel. Utilisez la carte de données conformément aux instructions ci-dessus avant de la retourner.
Si los mensajes son distintos, consulte el manual. Antes de devolverla, utilice la tarjeta tal como se indica.
Se as mensagens forem diferentes, consulte o seu manual. Use o cartão de dados tal como é descrito acima antes de o devolver.

Figure 9: Data Card mailback envelope

Use the mailback envelope for transporting and storing the Data Card. You can write your name and address details on the front of the mailback envelope to assist the patient in mailing it back to you. Use a postal envelope to mail the mailback envelope and its contents to the patient.

Inserting the Data Card

To insert the Data Card, the patient needs to:

1. Ensure the S8 Elite II is switched on and displaying the standby (RAMP) screen.
2. Insert the Data Card into the slot in the Data Card module (**H-1**). Continue inserting the Data Card smoothly until it stops moving (**H-2**) and messages start appearing on the LCD.

Removing the Data Card

To remove the Data Card, the patient needs to:

1. Grip the end of the Data Card and pull it out (**H-3**).
2. Place the Data Card in the mailback envelope supplied.

Transmitting Data with the Data Card

Copying Data onto a Data Card

If you want a patient to give you their data, you need to tell them how to copy data onto their Data Card.

Instruct the patient to carry out the following steps to copy data onto a Data Card:

1. With the device in standby (RAMP) mode, insert the Data Card into the slot on the Data Card module. Copying of data will start automatically.
2. The "Card Inserted Please Wait" message is displayed on the LCD while data is copied to the Data Card. Copying takes up to 30 seconds.
3. The "Copy Complete Remove Card" message is displayed on the LCD.
4. Remove the Data Card from the device. If mailing the Data Card and mailback envelope, put them in a postal envelope to send to the clinician.

This information is also supplied in the patient's User Guide.

Updating Settings on a Flow Generator

You can create new treatment settings and transfer them to a Data Card via a ResMed PC application. A patient can then use the Data Card to update the settings in their S8 Elite II. If you mail the Data Card to the patient, send it in the mailback envelope. If you need the Data Card sent back to you for verification, use a postal envelope to mail the mailback envelope and its contents to the patient.

Instruct the patient to carry out the following steps to update settings on their S8 Elite II:

1. With the device in standby (RAMP) mode, insert the Data Card into the slot on the Data Card module. Updating will start automatically.
2. The "Card Inserted Please Wait" message will appear on the LCD while updating is in progress. Updating takes up to 30 seconds.
3. The "Settings Success Remove Card" message is displayed on the LCD, if the settings were updated successfully.

Note: *This message only appears once. If you re-insert the Data Card after you have updated your settings, this message is not displayed.*

4. Remove the Data Card from the device. No additional data is copied onto the card once the "Copy Complete Remove Card" message is displayed, even if the card is left in the device. If mailing the Data Card and mailback envelope, put them in a postal envelope to send to the clinician.

This information is also supplied in the patient's User Guide.

When you create a Data Card with therapy settings you can store the serial number of the device on the Data Card. This prevents the settings from being applied to the wrong device. Refer to your PC application manual for more details.

Compliance and efficacy data are always stored in the S8 Elite II. If a Data Card is lost or damaged in transit, data stored in the S8 device can be recopied onto a Data Card.

WARNING

Advise the patient to contact you immediately if they are using the Data Card to update the settings on their device and the "Settings Success" message does not appear.

Analyzing the Data Card

Use a ResMed PC application to transfer data and settings between an S8 Elite II or a Data Card and your personal computer. Refer to the user guide for your PC application for more information about analyzing the information on returned Data Cards.

S8 Adapters

S8 adapters are designed for use with the ResMed S8 series of devices, to transfer data between the device and a personal computer.

Two adapters are available:

- Serial adapter, which uses a standard serial cable
- USB adapter (supplied with a USB cable).

WARNING

- Only use S8 adapters as specified in this manual.
- S8 adapters are specifically designed for use with ResMed S8 devices.

Attach the S8 serial or USB adapter to a ResMed S8 device to create a serial or USB port. You can then connect a cable that enables transfer of data between the device and a personal computer.

CAUTION

If a cable is not attached when an S8 adapter is attached to an S8 device, either attach the adapter's protective cover, or remove the adapter and replace it with a blank or Data Card module. This is to prevent damage to the S8 adapter.

Attaching an S8 adapter

Notes:

a. Ensure that a module or an adapter is attached to the S8 device at all times.
b. Remove the existing module from the S8 device if a serial or USB adapter is required.
c. The device should be turned off when removing a module and attaching an adapter.

To attach an S8 adapter to an S8 device:

1. Unplug the device from the wall.
2. Remove the module currently attached to the S8 device (**I-1**).

3. Press and hold down the button on the adapter (**I-2 a**), while pushing it onto the device.
4. Connect one end of the cable to the adapter and the other end to the computer.

Removing an S8 adapter

To remove the S8 adapter:

Notes: *The device should be turned off when removing an adapter and attaching a module.*

1. Press and hold down the button on the adapter (**I-3 a**), while pulling it off the S8 device.
2. Attach another module to the S8 device according to the instructions for that module.

See the manual for your PC application for information about downloading data to your computer.

Cleaning and Maintenance

You should regularly carry out the cleaning and maintenance described in this section. Refer to your mask manual for detailed instructions.

Daily Cleaning

Mask

Clean the mask according to the instructions supplied with the mask.

Air tubing

Disconnect the air tubing from the S8 Elite II (and humidifier, if used) and hang the tubing and mask in a clean, dry place until next use.

Humidifier

If you are using a humidifier, clean it according to the instructions in the humidifier user's manual.

Weekly Cleaning

1. Remove the air tubing from the S8 Elite II *and* the mask.
2. Wash the air tubing in warm water using mild detergent. Rinse thoroughly, hang, and allow to dry.
3. Before next use, assemble the mask and headgear according to the user instructions.
4. Reconnect the air tubing to the air outlet and mask.

Periodic Cleaning

1. Clean the exterior of the S8 Elite II with a damp cloth and mild liquid soap.
2. Check the air filter for blockage or holes (see "Replacing the Air Filter" on page 42).

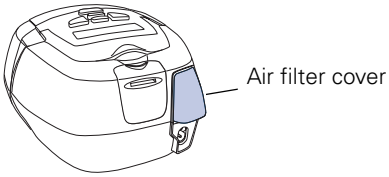
WARNING

- Beware of electric shock. Do not immerse the unit or power cord in water. Always unplug the unit before cleaning and be sure it is dry before plugging back in.
- The mask system and air tubing are subject to normal wear and tear. Inspect them regularly for damage.

Replacing the Air Filter

To replace the air filter:

1. Remove the air filter cover at the back of the S8 Elite II.



2. Remove and discard the old air filter.
3. Insert a new filter with the blue tinted side facing out from the device.
4. Replace the air filter cover.

Inspect the air filter every month to check if it is blocked by dirt or contains holes. With normal use of an S8 Elite II, the air filter needs to be replaced every six months (or more often if your device is in a dusty environment).

WARNING

- Do not wash the air filter. The air filter is not washable or reusable.
- The air filter cover protects the device in the event of accidental liquid spillage onto the device. Ensure the air filter and air filter cover are fitted at all times.

Servicing

CAUTION

- Do not attempt to open the S8 Elite II case. There are no user serviceable parts inside.
- Inspection and repair should only be performed by an authorized agent. Under no circumstances should you attempt to service or repair the flow generator yourself.

This product (S8 Elite II) should be inspected by an authorized ResMed service center 5 years from the date of manufacture. Prior to this, the device is intended to provide safe and reliable operation provided that it is operated and maintained in accordance with the instructions provided by ResMed. Applicable ResMed warranty details are provided with the device at the time of original supply. Of course, as with all electrical devices, if any irregularity becomes apparent, you should exercise caution and have the device inspected by an authorized ResMed service center.

If you feel that your flow generator is not performing properly, see "Troubleshooting" on page 45.

Frequently Asked Questions

Can patients use the S8 Elite II with a humidifier?

Yes. Patients may experience dryness of the nose, mouth and/or throat during the course of treatment, especially during winter. In many cases, a humidifier may resolve this discomfort. The S8 Elite II can be used with the HumidAire 3i to form an integrated device.

What is EPR?

EPR is designed to help patients who experience discomfort when breathing out against the pressure. If you set EPR, there are three levels available (1–3 cm H_2O) and two inhalation levels available (Medium and Fast). You can set EPR so that it is available either during ramping only, or throughout therapy. Use the EPR ACCESS menu setting to give the patient access to EPR level.

How can I obtain data or make data available to a patient?

Both the clinician and the patient can view data on the S8 Elite II LCD screen. You can also use a Data Card to obtain patient data and update patient settings data remotely. You can use an S8 adapter and cable to transfer data directly between an S8 Elite II and a PC application.

How long does the patient have to leave the Data Card in the S8 Elite II to collect data?

The Data Card can be inserted at any time. Data in the S8 Elite II will be transferred to the Data Card within 30 seconds.

How much data can I obtain from the S8 Elite II?

The S8 Elite II stores up to 365 days of summary data and up to five nights of detailed data (up to 500 events per session). The Data Card stores up to 180 days of summary data and up to four nights of detailed data (up to 200 events per session).

Can I set reminders for my patients?

You can set a series of reminders, to let patients know when to replace their mask or air filter, when to get their device serviced, when to use a Data Card, or when to contact you. You can use a PC application to customize specific reminders.

Can patients travel with the S8 Elite II?

International use

The S8 Elite II flow generator has an internal power supply that enables it to operate in other countries. It will operate on power supplies of 100–240V and 50/60Hz. No special adjustment is necessary, but patients will require an approved power cord for the region in which they are using the device.

Use on an aircraft

The S8 Elite II complies with US FCC Part 15, Class B requirements if no external data cables are used. Patients should consult the medical services department of their carrier if they intend to use their S8 Elite II on an aircraft.

Note: *Patients should not use their S8 Elite II while the aircraft is taking off or landing.*

Can patients use the S8 Elite II if mains (AC) power is not available?
There is a DC input socket at the rear of the S8 Elite II. A ResMed DC-12 converter must be used to connect the S8 Elite II to a 12V or 24V DC power source. The DC-12 converter is available separately from ResMed dealers.

WARNING
The device should not be connected to both AC and DC power sources simultaneously.

Troubleshooting

CAUTION

If the problem cannot be solved, contact your equipment supplier or ResMed. Do not attempt to open the S8 Elite II case. There are no user serviceable parts inside. Repairs and internal servicing should only be performed by an authorized service agent.

Problem	Possible Cause	Solution
No display.	Power is not connected.	Ensure the power cable is connected and the power switch (if available) is on.
Treatment pressure seems low.	Ramp Time is in use.	Wait for air pressure to build up.
	Air filter is dirty.	Replace air filter.
	Air tubing is kinked or punctured.	Straighten or replace tubing.
	Air tubing is not connected properly.	Check air tubing.
	Mask and headgear are not positioned correctly.	Adjust position of mask and headgear.
	Caps are missing from access port on mask.	Replace caps.
Device does not start when the patient breathes into the mask.	Power cord is not connected properly.	Connect power cord firmly at both ends.
	Power outlet may be faulty.	Try another power outlet.
	SmartStart not on.	Enable SmartStart.
	Leak Alert has been enabled; SmartStart has automatically been disabled.	Disable Leak Alert to enable SmartStart.
	Breath is not deep enough to trigger SmartStart.	Advise patient to take a deep breath in and out through the mask.

Problem	Possible Cause	Solution
	The patient is using a full-face mask.	SmartStart does not work with a full-face mask as the anti-asphyxia valve will not allow sufficiently high pressure on exhalation.
	There is excessive leak.	Adjust position of mask and headgear. Caps may be missing from ports on mask. Replace them. Air tubing not connected properly. Connect firmly at both ends. Air tubing kinked or punctured. Straighten or replace.
Device does not stop when the patient removes their mask.	SmartStart/Stop is not enabled.	Enable SmartStart/Stop.
SmartStart is enabled but the flow generator does not stop automatically when the patient removes their mask.	Incompatible mask system being used.	Use only equipment as recommended by ResMed.
Date or time in data files is wrong.	Date or time on device is wrong.	Correct the current time and date on the device.

Problem	Possible Cause	Solution
Displays error message: **Check tube!! Key if done**	The air tubing is loose or blocked.	Check that the air tubing is connected securely to your mask and the air outlet on the front of the S8 Elite II. When you have checked the air tubing, press the Start/Stop key to restart the device. If this does not clear the message, disconnect the power cord and then reconnect it to restart the device.
Displays error message: **SYS ERRORnnnn Call service!**	Component failure.	Record error number and contact the ResMed service centre.
Displays error message: **High leak in last session.**	Your patient has experienced leak levels of greater than 0.4 L/s (24 L/min) for more than 30% of the previous session.	Check air tubing connections and mask fit.
Displays error message: **HIGH LEAK!!! Adjust mask.**	Your patient has experienced leak levels of greater than 0.7 L/s (42 L/min) for more than 20 seconds.	Check air tubing connections and mask fit.
Display error message: **Exxxx** *(where* **xxxx** *defines an error)*	Component failure.	Return the S8 Elite II for servicing.
The Data Card is returned without the expected patient data.	Data Card was not inserted correctly.	Check that the patient is inserting the Data Card into the Data Card module with the arrow facing up, while the S8 Elite II is powered and not delivering therapy (in standby mode).
	Data Card was only partly inserted.	Check that the patient is inserting the Data Card as far as it will go into the slot on the Data Card module.

Problem	Possible Cause	Solution
	The card is not a ResScan Data Card.	Check that the card used is a ResScan Data Card.
The following message is displayed on the LCD after the patient inserts a Data Card: **Card Error** **Remove Card**	Data Card is not inserted correctly.	Check that the patient is inserting the Data Card into the Data Card module with the arrow facing up, while the S8 Elite II is switched on and not delivering therapy (standby mode).
	The card is not a ResScan Data Card.	Check that the card used is a ResScan Data Card.
	Data Card has been removed before the **Copy Complete** **Remove Card** message was displayed.	Advise the patient to reinsert the Data Card and wait for the **Copy Complete** **Remove Card** message to appear on the LCD.
	If this message occurs repeatedly even when the Data Card is inserted correctly, there may be a physical card fault on the Data Card.	Issue a new Data Card to the patient.
The following message is displayed on the LCD after the patient tries to update the settings using the Data Card: **Settings Invalid** **Remove Card**	The identification details on the Data Card do not match the identification details on the device the patient is trying to update.	Check that the identification details on the Data Card are correct. (See the clinician's manual for your PC application for instructions.)
The following message is displayed on the LCD after the patient tries to update the settings using the Data Card: **Settings Error** **Remove Card**	There is an unrecoverable data error on the Data Card.	Use the appropriate PC application to reprogram the settings on a new Data Card and issue it to the patient.

Problem	Possible Cause	Solution
The following message is NOT displayed on the LCD after the patient tries to update the settings using the Data Card: **`Settings Success Remove Card`**	The settings were not updated.	The message only appears the first time a Data Card is inserted into a device to update settings. The patient may have missed seeing the message. To check whether the settings have actually been applied: • Ask the patient whether the therapy they are receiving feels different. • Check the settings data written on the Data Card from the S8 Elite II to see if they are correct (refer to your PC application clinician's manual for more information). If the settings data on the Data Card matches the intended settings the device has been programmed successfully.

If the patient doesn't feel any difference in therapy and/or the settings are not correct, you need to consider the following possible causes:

	Data Card given to patient did not contain settings because the patient received the wrong card.	Use the appropriate PC application to reprogram the Data Card with the settings, and reissue it to the patient.
	The Data Card was removed before settings were copied to the S8 Elite II.	Check that the patient does not remove the Data Card before the **`Settings Success Remove Card`** message appears on the LCD.

Problem	Possible Cause	Solution
	Data Card given to patient did not contain settings because programming of settings did not complete.	Use the appropriate PC application to reprogram the Data Card with the settings, making sure that programming completes. Reissue the card to the patient.
	Data Card was not inserted correctly.	Check that the patient is inserting the Data Card into the Data Card module with the arrow facing up, while the S8 Elite II is switched on and not delivering therapy (standby mode).
	Data Card was only partly inserted.	Check that the patient is inserting the Data Card as far as it will go into the slot on the Data Card module.
	The card is not a ResScan Data Card.	Check that the card used is a ResScan Data Card.

System Specifications

S8 Elite II (without Accessories)

Performance

Operating pressure range: 4 to 20 cm H_2O
Dimensions (H x W x D): 4.4″ x 6.5″ x 5.7″ (112 mm x 164 mm x 145 mm)
Weight: 3.1 lb (1.4 kg)

Power Supply

- Input range for S8 Elite II with HumidAire 3i: 100–240V, 50/60Hz; 110V, 400Hz; 2.5A <140VA (110 W) (maximum power consumption). Instantaneous peak power consumption <340VA.
- Refer to the DC-12 converter instructions for DC ratings. Only use the ResMed DC-12 converter for DC input.

Actual power consumption will vary, depending on factors such as the use of accessories, height above sea level and ambient temperature. Power consumption values for typical treatment conditions (using a breathing machine set to 0.5L and 15 breaths/min with 6′6″[2 m] air tubing and an Ultra Mirage mask) are given in the following table.

Device	Pressure (cm H_2O)	Power (VA)	Power (W)
S8 Elite II	5	18	7.6
	10	23	11.6
	15	30	15.9
	20	39	20.7

Power outlet for HumidAire 3i
Outlet range: 100–240V, 50/60Hz; 110V, 400Hz; 2.0A
Air Filter: Two-layered, powder-bonded, polyester non-woven fiber
Air Tubing: Flexible plastic, 6′6″ (2 m)
Air Outlet: The 22 mm conical air outlet complies with EN 1281-1
IEC 60601-1 Classifications: Class II (double insulation), Type CF

Noise Level

S8 Elite II—CPAP mode, 10 cm H_2O set pressure[a]	
Measured total A-weighted sound pressure level (dB re 20 µPa)	24 dBA
Uncertainty (dB re 20 µPa)	2 dBA
Measured values are determined according to the noise test procedure given in ISO 17510-1. ***Note:*** *The sum of a measured noise emission value and its associated uncertainty represents an upper boundary of the range of values that is likely to occur in measurements.*	

a Declared dual number noise emission values in accordance with ISO 4871.

Accessories

Data Card

Dimensions (L x W x D): 2.56″ x 0.87″ x 0.03″ (65.04 mm x 22.15 mm x 0.85 mm)

Data Card Module

Dimensions (H x W x D): 1.95″ x 1.66″ x 0.47″ (49.7 mm x 42.2 mm x 12 mm)

S8 Serial and USB Adapters

Dimensions (H x W x D): 1.64″ x 1.67″ x 1.57″ (41.8 mm x 42.8 mm x 40 mm)

All Devices (where applicable)

Housing Construction: Flame retardant engineering thermoplastic

Environmental Conditions

Operating Temperature: +41°F to +97°F (+5°C to +36°C)
Operating Humidity: 10%–95% non-condensing
Storage and Transport Temperature: -4°F to +140°F (-20°C to +60°C)
Storage and Transport Humidity: 10%–95% non-condensing

Operating Altitude: Sea level to 8500′ (2591 m)

Electromagnetic Compatibility

The electromagnetic compatibility tables for this ResMed device can be found on **www.resmed.com**, on the **Products** page under **Service and Support**. Click on the PDF file for your device.

Note: *The manufacturer reserves the right to change these specifications without notice.*

Symbols which appear on the device

Attention, consult accompanying documents

Type CF equipment

Class II equipment

Drip proof

Dangerous voltage

Start/Stop and Mask-fit

INDEX

A
accessories 8
adapters
  removing 40
  serial 39
  USB 39
air filter 51
  replacing 42
air tubing 51
  cleaning 41
aircraft 43
apnea 32
attaching an adapter 39

B
baud rate 25
blank module 35

C
call provider reminder 26
cleaning 41
  daily 41
  periodic 41
  weekly 41
cleaning mask 41
Clinical Menu
  used days/total days 23
  used hours 23
Clinical menu
  EPR Inhale 23
  EPR Level 23
clinical menu 18
  baud rate 25
  CPAP 23
  Date 24
  Efficacy Data 24
  EPR 23
  EPR Access 24
  EPR Level 23
  Erase Data 24, 31
  Factory Defaults 24
  Humid 23
  Language 24
  Leak Alert 23
  Mask 23
  Max Ramp 23
  Menu Type 24
  Mode 23
  Options menu 24
  parameters 23
  PCB number 25
  quick key access 15
  Ramp 23
  Reminders 24, 25
  Results 29
  Run Hours 25
  serial number (device) 25
  Servicing Menu 25
  Settings Menu 23
  Smart Data 24
  SmartStart 23
  software version 25
  Start CPAP 23
  Time 24
  Tube Length 23
  Usage Data 24
clinical menu results
  data 29
CPAP 23
CPAP menu 15
customized reminders 26

D
daily cleaning 41
data
  clinical menu results 29
Data Card 43
  analyzing 39
  copying data to 38
  inserting 37
  patient management 35
  removing 37
  updating settings 38
Data Card module 35
data management 29
data management products 8, 35
date (setting) 24
DC-12 converter 44
delivering therapy 11
detailed data 43
down key 14
dryness
  mouth, nose, or throat 43

E
Efficacy Data 24
Electromagnetic 52
Electromagnetic Compatibility 52
environmental conditions 52
EPR 43
  device performance 10
  screens 23
EPR Access 24
EPR Inhale 23
EPR Level 23
EPR screens 23
Erase Data 24, 31
expiratory pressure relief 9

F
Factory Defaults 24
frequently asked questions 43, 44
front cap 23

H
high leak message 32
housing construction 52
HumidAire 3i 8
  attaching 13
  storing 13
humidifier 43
  cleaning 41
  type 8
hypopnea 32

I
insert card reminder 26
international use 43
interpreting data 31

K
keypad 14

L
Language 24
LCD screen 14
Leak Alert 23
left key 15

M
machine hours 25
mailback envelope 37
Mask 23
mask
  available masks 7
  mask-fit 13
mask settings 25
mask types 25
maximum ramp 23
median values 31
medical information 3
Menu Type 24
menus 15
Mode 23
modules
  blank 35
  Data Card 35

N
Noise level 52

O
obstructive sleep apnea (OSA) 9
obtaining data 43
operating information 7
Options menu 24

P
patient management
  Data Card 35
patient menu 15
  Humid 23
  Language 24
  Leak Alert 23
  Mask 23
  parameters 23
  PCB number 25
  Ramp 23
  Run Hours 25
  serial number (device) 25
  Smart Data 24, 32
  SmartStart 23
  software version 25
  Tube Length 23
periodic cleaning 41
power sources 44
power supply 51
principles of operation 9
printed circuit board number 25

Q
quick key access
  clinical menu 15

R
Ramp 23
Recurring reminders 27
Reminders 24

reminders 24, 25, 43
  call provider 26
  customized 26
  insert card 26
  replace air filter 26
  replace mask 26
  service due 26
removing an adapter 40
replace air filter reminder 26
replace mask reminder 26
responsibility, user/owner 1
Results 29
right key 15
Run Hours 25

S

S8 adapter 43
S8 adapters
  dimensions 52
  removing 40
  serial 39
  USB 39
S8 Elite II 7
  dimensions 52
  servicing 42
  travelling with 43
serial adapter 39
serial number 25
service due reminder 26
Servicing Menu 25
setting 14
Settings Menu 23
Smart Data 24
  displaying patient data 32
  patient menu 32
SmartStart 11, 23
software version 25
star ratings, mask fit 13
Start CPAP 23
start/stop key 14
statistics
  median values 31
summary data 43
system specifications
  S8 Elite II 51

T

technical specifications 52
time (setting) 24
troubleshooting 45
Tube Length 23

U

up key 14
updating device settings 38
Usage Data 24
USB adapter 39
use on aircraft 43
used hours 23
Used screen
  clinical menu 29
user/owner responsibility 1
using Data Card 37

W

weekly cleaning 41
weight 51